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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/363,100	07/29/1999	DONALD A.G. MICKLE	50074/004003	7723

30091 7590 03/03/2003

CLARK & ELBING LLP  
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BOSTON, MA 02110

EXAMINER
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AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.  
**09/363,100**

Applicant(s)  
**Mickle et al.**

Examiner  
**Vera Afremova**

Art Unit  
**1651**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Dec 26, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Dec 26, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none

Claim(s) objected to: none

Claim(s) rejected: 1, 2, 4-11, 13, and 25-28

Claim(s) withdrawn from consideration: 14-24

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other:

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**Attachment to the Advisory Action**

The amendment filed 12/26/2002 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because the proposed amendment raises new issues that would require further consideration and/or search with regard to the newly proposed limitation drawn to the survival of the administered cellular suspension of mesenchymal stem cells in the cardiac scar tissue of patient (claim 1). The new issues, including 112-2 issues, are also related to the improvement of heart function as the result of survival of the administered cellular suspension of mesenchymal stem cells in cardiac scar tissue of patient (claim 1) since it is uncertain what are the criteria of improvement. Although some of the proposed amendment which are drawn to the improvement of heart function appear to be intended for resolving the new matter rejection raised in the last office action, the proposed amendment as the whole is not deemed to place the application in better form for appeal by materially simplifying the issues by for appeal.

***Response to Arguments***

Applicants' arguments filed 12/26/2002 have been fully considered but they are not found particularly persuasive.

Applicants' main argument appears to be directed to the idea that the cited references do not teach or suggest the site of administration of cells including mesenchymal stem cells such as a cardiac scar tissue. However, the cited references by Robinson et al. and by Murry et al. encompass transplantation into cardiac scar tissue of cells belonging to myogenic lineage for

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treating and improving heart function. The cited patent US 5,736,396 teaches method of administration of mesenchymal stem cells including the mesenchymal stem cells induced towards myogenic lineage to patient in need thereof, wherein it is reasonably to expect that the site of administration of cells of myogenic lineage is a damaged cardiac tissue as taught by Robinson et al. and by Murry et al in the methods for improving heart function.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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February 25, 2003.



**IRENE MARX**  
**PRIMARY EXAMINER**